

AMENDMENTS TO THE CLAIMS

1-9. (Canceled)

10. (Currently amended) A process for preparing an alkali metal clavulanate salt agglomerate randomly ordered crystal agglomerates comprising an alkali metal clavulanate salt, with the proviso that the rosette-like crystalline form of potassium clavulanate is excluded, which comprises contacting a solution or suspension of a pharmaceutically acceptable alkali metal clavulanate salt in a solvent or mixture of solvents with one or more anti-solvents under stirring to cause precipitation of an agglomerate comprising pharmaceutically acceptable alkali metal clavulanate crystals, wherein said agglomerate is substantially free from non-agglomerate crystals in the needle form and is other than the rosette-like crystalline form of potassium clavulanate.

11. (Canceled)

12. (Previously presented) A process according to claim 10, wherein the ratio of the weight of the solution containing the clavulanate salt to the anti-solvent is about 0.05 to 10 wt.%.

13. (Previously presented) A process according to claim 10, wherein the solvent is water, ethanol, or a mixture thereof, wherein water is present in said mixture.

14. (Previously presented) A process according to claim 10, wherein the anti-solvent is a ketone, an ester, or an alcohol, or a mixture thereof, optionally containing water.

15. (Canceled)

16. (Previously presented) A process according to claim 10, wherein the stirring is performed by applying stirring devices in one or more vessels, in-line mixers or a combination thereof.

17. (Previously presented) A process according to claim 16, wherein the stirring device is a high shear mixer.

18. (Previously presented) A process according to claim 10, wherein said stirring is performed by combining and permuting different stirring devices, the speeds of said devices, the type and amount of the solvents used, and mixing one or more solvents and anti-solvents.

19. (Currently amended) A process according to claim 18, wherein the agglomerates ~~have~~ has an average particle size between about 1 μm and 1500 μm .

20. (Previously presented) A process according to claim 10, wherein the process comprises dissolving the alkali metal clavulanate salt in a solvent, adjusting the pH to about neutral and mixing with the anti-solvent.

21-26. (Canceled)

27. (Currently amended) A process according to claim 19, wherein the agglomerates ~~have~~ has an average particle size about 100 μm .

28. (Currently amended) A process according to claim 19, wherein the agglomerates ~~have~~ has an average particle size about 1000 μm .

29. (Currently amended) A process according to claim 10, wherein the agglomerates ~~have~~ has a bulk density between about 0.20 g/mL and 0.60 g/mL.

30. (Canceled)

31. (Currently amended) A process according to claim 10, wherein the agglomerates ~~have~~ has a ~~Carr index~~ compressibility between about 10 % and 40 %, calculated as 100 times the ratio of the difference between tapped bulk density and loose bulk density to the tapped bulk density.

32. A process according to claim 10, wherein said alkali metal clavulanate salt is potassium clavulanate.

33. (Canceled)

34. (Currently amended) A process according to claim 32, wherein the agglomerates further comprises amoxicillin.

35. (Currently amended) A process according to claim 10, wherein the agglomerates optionally contains one or more excipients.

36. (Previously presented) A process according to claim 35, wherein the one or more excipients are selected from the group consisting of microcrystalline cellulose and silica.

37. (Currently amended) An agglomerate comprising pharmaceutically acceptable alkali metal clavulanate crystals, wherein said agglomerate is substantially free from non-agglomerated crystals in the needle form of randomly ordered crystals of an alkali metal clavulanate salt having a Carr index compressibility of between about 10% and 40%, with the proviso that the rosette-like crystalline form of potassium clavulanate is excluded.

38. (Canceled)

39. (Previously presented) The agglomerate of claim 37, further comprising amoxillin.

40. (Previously presented) The agglomerate of claim 37, further comprising one or more excipients.

41. (Previously presented) The agglomerate of claim 40, wherein said one or more excipients is selected from the group consisting of microcrystalline cellulose and silica.

42. (Previously presented) The agglomerate of claim 37, wherein said agglomerate has an average particle size between about 1 μm and 1500 μm .

43. (Previously presented) The agglomerate of claim 42, wherein said agglomerates has an average particle size of about 100 μm .

44. (Previously presented) The agglomerate of claim 42, wherein said agglomerate has an average particle size of about 1000 μm .

45. (Canceled)

46. The agglomerate of claim 37, wherein said alkali metal clavulanate salt is potassium clavulanate.

47. (Previously presented) A pharmaceutical formulation comprising the agglomerate of claim 37 and one or more pharmaceutically acceptable excipients.

48. (Previously presented) The pharmaceutical formulation of claim 47, further comprising amoxicillin.

49. (Previously presented) The pharmaceutical formulation of claim 47, wherein said one or more pharmaceutically acceptable inert excipients is selected from the group consisting of microcrystalline cellulose and silica.

50. (Previously presented) A pharmaceutical dosage form comprising a pharmaceutical formulation of claim 47.

51. (Previously presented) The agglomerate of claim 37, wherein said agglomerate has a loose bulk density of between about 0.2 g/mL and 0.6 g/mL.

52. (Previously presented) The agglomerate of claim 37, wherein said agglomerate have a weight percentage between 0-10% of non-agglomerates.

53. (Previously presented) The process of claim 10, wherein said agglomerates have a weight percentage between 0-10% of non-agglomerates.

54. (Previously presented) The process of claim 10, wherein the solvent is aqueous acetone.

Please add the following new claims:

55. (New) A process for preparing potassium clavulanate in the form of an agglomerate, comprising contacting potassium clavulanate in water or ethanol, and contacting the resulting solution with an anti-solvent under stirring to cause precipitation of an agglomerate comprising potassium clavulanate crystals, wherein said agglomerate is substantially free from non-agglomerate crystals in the needle form and is other than the rosette-like crystalline form of potassium clavulanate.

56. (New) The process of claim 55, wherein the potassium clavulanate in water further comprises acetone.

57. (New) The process of claim 55, wherein said anti-solvent comprises acetone or ethyl acetate.